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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,805	03/13/2001	Shuqian Jing	MBHB01-006-A1	6328

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EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/805,805	Applicant(s) JING ET AL.	
	Examiner Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method for producing an FGF-L polypeptide comprising isolated nucleic acid molecules, vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

II. Claim 12, drawn to a method of determining whether a compound inhibits FGF-L polypeptide activity or FGF-L polypeptide production, classification dependent upon structure of compound.

III. Claims 13-17, 37-41, and 45-46 drawn to an isolated polypeptide, pharmaceutical compositions, derivatives, and modifications thereof comprising same, classified in class 530, subclass 350, for example.

IV. Claims 18-32 drawn to an antibody immunospecific for a polypeptide and pharmaceutical compositions comprising the same, classified in class 530, subclass 387.1, for example.

V. Claim 33, drawn to a method of treating, preventing, or ameliorating an FGF-L polypeptide-related disease, condition, or disorder comprising administering to a patient an effective amount of an antibody, classified in class 424, subclass 130.1, for example.

VI. Claim 34 drawn to a selective binding agent produced by immunizing an animal with a polypeptide, classified in class 530, subclass 387.1, for example.

VII. Claim 35 drawn to a hybridoma which produces a selective binding agent that is capable of binding a polypeptide, classified in class 435, subclass 326, for example.

VIII. Claim 36 drawn to a method of detecting or quantitating the amount of FGF-L polypeptide using an antibody, classified in class 435, subclass 7.1, for example.

IX. Claims 42-44, drawn to gene therapy compositions, classified in class 514, subclass 44, for example.

X. Claim 47, drawn to a method of treating, preventing, or ameliorating a medical condition comprising administering a polypeptide to a patient, classified in class 514, subclass 2, for example.

XI. Claim 48, drawn to a method of diagnosing a pathological condition or susceptibility to a pathological condition in a subject comprising determining the presence or amount of expression of a polypeptide, classification dependent upon how expression is measured.

XII. Claim 49, drawn to a device, classified in class 604, subclass 890.1, for example.

XIII. Claims 50 and 51, a method of identifying a compound which binds to an FGF-L polypeptide, classification dependent upon structure of compound.

XIV. Claim 52 drawn to a method of modulating levels of a polypeptide in an animal comprising administering a nucleic acid molecule to an animal, classified in class 800, subclass 2, for example.

XV. Claim 53 drawn to a transgenic non-human animal, classified in class 800, subclass 9, for example.

XVI. Claim 54 drawn to a process for determining whether a compound inhibits FGF-L polypeptide activity or FGF-L polypeptide production comprising exposing a transgenic mammal to a compound, classification dependent upon structure of compound.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, V, VIII, X, XI, XIII, XIV, and XVI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of producing an FGF-L polypeptide, which is not required by any of the other Inventions. Invention II requires search and consideration of whether a compound inhibits FGF-L polypeptide activity or production, which is not required by any of the other Inventions. Invention V requires search and consideration of treating, preventing or ameliorating an FGF-L polypeptide-related disease, condition, or disorder by administering an antibody, which is not required by any of the other Inventions. Invention VIII requires search and consideration of detecting or quantitating the amount of FGF-L polypeptide using an antibody, which is not required by any of the other Inventions. Invention X requires search and consideration of treating, preventing or ameliorating a medical condition by administering a polypeptide, which is not required by any of the other Inventions. Invention XI requires search and consideration of diagnosing a pathological condition or susceptibility to a pathological

condition in a subject, which is not required by any of the other Inventions. Invention XII requires search and consideration of a device, which is not required by any of the other Inventions. Invention XIII requires search and consideration of identifying whether a compound binds FGF-L polypeptide, which is not required by any of the other Inventions. Invention XIV requires search and consideration of a method of modulating levels of a polypeptide in an animal comprising administering a nucleic acid molecule to an animal, which is not required by any of the other Inventions. Invention XV requires search and consideration of a transgenic non-human animal, which is not required by any of the other Inventions. Invention XVI requires search and consideration of a method comprising exposing a transgenic mammal to a compound, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions III, IV, VI, VII, IX, XII, and XV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The isolated polypeptide of Invention III is independent and distinct from the products of Inventions VII, XII, and XV because none are required to make or use the isolated polypeptide of Invention I. Further, the isolated polypeptide of Invention III can be prepared by processes which are materially different from the antibody of Invention IV, the selective binding agent of Invention VI, or the nucleic acid component of the gene therapy composition of Invention IX, such as by chemical synthesis, or by isolation and purification from natural sources. The antibody of Invention IV is independent and distinct from the products of

Inventions VI, VII, IX, XII, and XV because none are required to make or use the antibody of Invention IV. Although the antibody of Invention IV can be used to obtain the polypeptides of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The selective binding agent of Invention VI is independent and distinct from the products of Inventions IV, IX, XII, and XV because none are required to make or use the selective binding agent of Invention VI. Although the selective binding agent of Invention VI can be used to obtain the polypeptides of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Further, the selective binding agent of Invention VI can be prepared by processes which are materially different from hybridoma of Invention VII, such as by chemical synthesis, or by isolation and purification from natural sources. The hybridoma of Invention VII is independent and distinct from the products of Inventions IV, VI, IX, XII, and XV because none are required to make or use the hybridoma of Invention VII. Although the hybridoma of Invention VII can be used to obtain the polypeptide of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The gene therapy composition of Invention IX is independent and distinct from the products of Inventions III, IV, VI, VII, XII, and XV because none are required to make or use the gene therapy composition of Invention IX. The device of Invention XII is independent and distinct from the products of Inventions III, IV, VI, VII, IX, and XV because none are required to make or use the device of Invention XII. The transgenic animal of Invention XV is independent and distinct from the products of Inventions III, IV, VI,

VII, and XII because none are required to make or use the transgenic animal of Invention XV. Further, the transgenic animal of Invention XV can be prepared by processes which are materially different from the nucleic acid component of the gene therapy composition of Invention IX, such as by animal husbandry methods, selective breeding, or irradiation of the germ cells and screening of the subsequent offspring.

5. Inventions III and II, VIII, X, XI, XIII, and XVI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Invention III can be used in a materially different process other than determining whether a compound inhibits FGF-L polypeptide as in Invention II, detecting or quantitating FGF-L polypeptide as in Invention VIII, the therapeutic methods of Inventions X and XI, the method of identifying a compound that binds FGF-L polypeptide as in Invention XIII, or the method using a transgenic animal to identify a compound that inhibits FGF-L polypeptide as in Invention XVI, such as being used to make the antibody of Invention IV.

6. Inventions IV and each of V, VIII, X, XI, and XIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Invention IV can be used in a materially different process of used in materially different processes other than to treat

FGF-L related diseases in Invention V, detect or quantitate FGF-L in Invention VIII, treat a medical condition in Invention X, or diagnose a pathological condition in Invention XI, such as isolating receptors in a biochemical assay.

7. Inventions IX and each of I and XIV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid molecule component of the gene therapy composition of Invention IX can be used in processes other than to make polypeptides in Invention I or to module levels of polypeptides in an animal in Invention XIV, such in gene therapy or as a probe in nucleic acid hybridization assays.

8. Inventions XV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animal of Invention XV could be used in a materially different process such as producing FGF-L peptide for extraction and purification.

9. Inventions I and XII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device of Invention XII could be used to deliver insulin into the blood stream.

10. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptides of Invention III can be prepared by processes which are materially different from recombinant DNA expression of Invention I, such as by chemical synthesis, or by isolation and purification from natural sources.

11. Inventions III and each of V and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of V and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V and XIV do not recite the use or production of the polypeptides of Invention III.

12. Inventions IV and each of I, II, X, XI, XIII, XIV, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of I, II, X, XI, XIII, XIV, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, X, XI, XIII, XIV, and XVI do not recite the use or production of the antibody of Invention IV.

13. Inventions VI and each of I, II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of I, II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, V, VIII, X, XI, XIII, XIV, and XVI do not recite the use or production of the selective binding agent of Invention VI.

14. Inventions VII and each of I, II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of I, II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, V, VIII, X, XI, XIII, XIV, and XVI do not recite the use or production of the hybridoma of Invention VII.

15. Inventions IX and each of II, V, VIII, X, XI, XIII, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and each of II, V, VIII, X, XI, XIII, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, V, VIII, X, XI, XIII, and XVI do not recite the use or production of the gene therapy compositions of Invention IX.

16. Inventions XII and each of II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of I, II, V, VIII, X, XI, XIII, XIV, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, V, VIII, X, XI, XIII, XIV, and XVI do not recite the use or production of the device of Invention XII.

17. Inventions XV and each of I, II, V, VIII, X, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XV and each of I, II, V, VIII, X, XI, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, V, VIII, X, XI, XIII, and XIV do not recite the use or production of the transgenic animal of Invention XV.

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

19. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-54, each in part, as the inventions pertain to SEQ ID NO: 1.

B. Claims 1-54, each in part, as the inventions pertain to SEQ ID NO: 2.

20. The inventions are distinct, each from the other because of the following reasons:

21. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A and B are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention A requires search and consideration of SEQ ID NO: 1, which is not required by the other Invention. Invention B requires search and consideration of SEQ ID NO: 2, which is not required by the other Invention. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to both sequences would therefore present the examiner with an undue search burden.

22. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-XVI. In order to be fully responsive, Applicant must elect one group from I-XVI and one group from A or B.

23. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Polyethylene glycol

b. Monomethoxypolyethylene glycol

c. Dextran

d. Cellulose

e. Poly-(N-vinyl pyrrolidone) polyethylene glycol

f. Propylene glycol homopolymers

g. Polypropylene oxide/ethylene oxide copolymers

h. Polyoxyethylated polyols

i. Polyvinyl alcohol

24. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 41 is generic.

25. If applicant selects Invention III, one species from the water-soluble polymers group must be chosen to be fully responsive.

26. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

27. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

28. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

29. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 25, 2002

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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